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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
SHERR-UNA BOOKER, an individual, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**PLAINTIFF, SHERR-UNA BOOKER'S RESPONSE TO DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT ON PLAINTIFF SHERR-UNA BOOKER'S CLAIMS**

In their Motion for Partial Summary Judgment as to Sherr-una Booker's Claims, Defendants seek summary judgment on four claims[1] and Plaintiff's ability to recover punitive damages. The facts and reasonable inferences from the facts, construed in the light most favorable to Plaintiff, allow Plaintiff's claims to go to the jury. Accordingly, this Court should deny the Motion as to the failure to warn counts, II and VII, the misrepresentation counts, VIII and XII, the negligence *per se* claim, IX, and the claim for punitive damages.

I. Introduction and Summary of Argument

Plaintiff Sherr-una Booker [redacted]. At the time, Bard knew its IVC filters (including the G2 and Recovery filters, the predicate to the [redacted] Ms. Booker [redacted]) fractured, migrated, tilted, and perforated patients' IVCs at rates significantly higher than its competitors' IVC filters and Bard's own Simon Nitinol Filter ("SNF"). Bard also had internally concluded that it's the IVC filters caused an unreasonable risk of serious injury and death. Nonetheless, Bard did not warn implanting physicians—including Ms. Booker's [redacted]—of these significantly higher risks or of its determination that Ms. Booker's [redacted] presented an unreasonable risk of harm. Ms. Booker's [redacted].

On the failure-to-warn and misrepresentation claims, Bard asserts that it had no duty to warn doctors of the significantly increased rate of failure associated with its devices or of its determination that its devices carried an unreasonable risk of harm. However, this very issue was decided against Bard in *Cason v. C.R. Bard, Inc.*, 2015 WL

[1] Plaintiff's claims are 1) manufacturing defect (Counts I, V); 2) failure-to-warn (Counts II & VII) and misrepresentation (VIII & XII); 3) failure to recall/retrofit (Count VI); and 4) negligence per se (IX). Plaintiff withdraws Counts I and V related to manufacturing defect and Count VI related to failure to recall/retrofit.

[2] Defendants C.R. Bard, Inc. and Bard Peripheral Vascular are referred to herein collectively as "Bard."

9913809 (N.D. Ga. Feb. 9, 2015). There, Judge Shoob of the Northern District of Georgia *rejected* Bard's argument over the same warnings at issue here for the same device, the G2. Based on Georgia law, Judge Shoob found that there was a "genuine issue of fact" for the jury as to whether Bard's warnings were adequate and should have included that the G2 experienced complications at significantly higher rates than other manufacturer's IVC filters and the SNF. *Id.* at *3-4. *Cason* is not the only case where Bard has lost on this issue. In *Cisson v. C.R. Bard, Inc.*, 2013 WL 5700513, at *7 (S.D. W.Va. Oct. 18, 2013), Judge Goodwin came to the same conclusion; applying Georgia law, he rejected Bard's argument that "its duty was limited to warning[s] about possible complications, not their rate or severity" and found evidence of higher complication rates with Bard devices sufficient to create a jury question as to the adequacy of the warnings.

Bard's other warnings arguments likewise fail because they are premised on its incorrect assertion that its warnings need not include anything more than generic complications for all IVC filters. Bard's argument as to negligence *per se* fares no better, since it is predicated entirely on the false premise that Plaintiff's claims are preempted. Finally, Bard's argument as to punitive damages ignores the enormity of the evidence concerning Bard's wrongful and egregious conduct (including Bard's decision to ignore proven design changes in favor of profit). Because the evidence permits a reasonable inference that Bard engaged in a course of conduct that knowingly endangered those using its product—resulting in multiple deaths and numerous significant injuries—punitive damages is a question of fact for the jury.

II. Facts

This case arises from injuries Plaintiff Sherr-una Booker suffered [redacted]. *See* Sherr-una Booker's Supplement to Plaintiffs' Omnibus Statement of Facts ("OSOF-Supp.") ¶ 315 filed concurrently herewith. [redacted]

[redacted]. *Id.* ¶ 318.

At the time of implant in Ms. Booker, the G2 had been cleared for permanent indication only. *See* Plaintiffs' Omnibus Statement of Facts ("OSOF") [Doc. 7950] ¶ 71. Bard's labeling represented that the G2 Filter was safe and effective for permanent implantation in the human body for the prevention of pulmonary embolism. *Id.* ¶ 67. Bard's "Patient Questions & Answers" document for the G2 filter states that the G2 filter is designed to be a permanent implant and will not need to be removed, repositioned, or replaced. *Id.* ¶ 68. Dr. [redacted] testified that the decision to remove an IVC filter has evolved over the years, and it is now a part of his practice to advise patients to return for follow-up to have filter retrieved. OSOF-Supp. ¶ 343. Dr. [redacted] testified that when he [redacted] Ms. Booker it had only been cleared for permanent implantation and he was implanting the filter as a permanent filter in 2007. *Id.* Dr. [redacted] testified that he intended [redacted] Ms. Booker. *Id.*

At the time of Ms. Booker's [redacted], Bard's SNF was still available on the market for implantation as a permanent IVC filter, yet Bard was marketing the G2 as an improved version of the SNF. OSOF ¶¶ 69, 75, 76, 80, 113. Prior to Ms. Booker's implantation, Bard was aware of the following facts relating to the G2 and its predicate device, the Recovery:

- In its sole clinical study for the Recovery filter, the filter in one of the 32 study patients had two fractures, OSOF ¶ 10; after the fractures were reported, the Canadian Institutional Review Board suspended the study. *Id.* ¶ 11. That same study also involved two tilted filters, one migration, and one perforation of the IVC. *Id.* ¶ 10.
- Subsequent comparative bench testing for migration resistance demonstrated that the Recovery filter: (a) performed worse than the SNF at every caval diameter, (b) performed worse than almost all competitor devices at every caval diameter, and (c) failed Bard's own performance threshold for resistance at 28 mm. *Id.* ¶ 34.
- Two months after full market release of the Recovery, Bard national sales training manager stated: "Tilt resistance should probably be downplayed." Its marketing director acknowledged, "We knew very little about the long-term clinical performance of this device when we launched it. After a year of commercialization, there are still many questions that need to be answered." *Id.* ¶ 33(b) and (c).

- In the first 12 months after full market release, there were seven deaths resulting from migration of the Recovery filter to patients' hearts. *Id.* ¶ 48.

- By April 2004, Bard knew that the Recovery filter was designed in a way that did not account for how the IVC actually behaved. *Id.* ¶ 41.

- In the midst of the migration deaths from the Recovery filter, Bard developed a Crisis Communication Plan, which included a messaging instruction from a team member that "[c]omparison with other filters is problematic in many ways and we should avoid/downplay this as much as possible. When pressed, we simply paraphrase … that estimates based on the available data suggest that there is no significant difference in the rates of these complications between any of the devices currently marketed in the U.S., including the Recovery device." *Id.* ¶ 45.

- By May 2004, Bard determined that, based on complications, "[a]t a 95% confidence, there IS a significant difference between Recovery, Gunther Tulip, Bird's Nest and SNF." *Id.* ¶ 49(d).

- By July 9, 2004, Bard determined that the Recovery had a fracture rate that was tens of times higher than other filters on the market. *Id.* ¶ 49(a).

- By November 2, 2004, Bard knew of 32 Recovery filter fractures. *Id.* ¶ 56.
  - Of those 32, nine fragments had traveled to the heart or lungs of patients, including three open heart surgeries to retrieve fragments. *Id.* ¶ 138.

- By December 2004, Bard determined that the Recovery filter had reporting rates of complications as compared to all other filters, including the SNF, as follows:
  - for deaths, 4.6 times higher;
  - for migrations, 4.4 times;
  - for IVC perforations, 4.1 times higher; and
  - for fractures, 5.3 higher times higher.

  Bard concluded that "[t]hese differences were all statistically significant." *Id.* ¶ 57.

- In January 2005, Bard's internal analysis revealed that "the data and [a consultant's] analysis provided two significant signals that further investigation particularly in relation to migration and fracture is urgently warranted." *Id.* ¶ 59.

- According to Bard's current Quality Engineering Manager for New Product Development, Natalie Wong, the Recovery was worse than the SNF with regard to filter-related deaths and filter fracture. *Id.* ¶ 38.

- On August 3, 2005, an internal report from Bard's VP of Regulatory/Science reported 68 fractures—25 of which involved fragments embolizing to the heart or lung. *Id.* ¶ 62.

- Despite advertising the G2 filter as being 12 times more resistant to fracture, Bard did not run a test for fracture resistance because it concluded that the resulting data "would still fall outside of the acceptable range" and it "didn't think the answer would support our design change." *Id.* ¶ 76.

- Bard knew that comparatively the SNF was a significantly safer device than the G2 filter. In December 2005, Dr. Ciavarella, Bard's Corporate Clinical Affairs Director, noted the complications with the G2 filter and stated: "The G2 is a permanent filter; we also have one (the SNF) that has virtually no complaints

associated with it. 'Why shouldn't doctors be using that one rather than the G2?'" *Id.* ¶ 80.

- In December 2005, internal Bard reports determined that the "reported rate of fractures [was] judged to be serious (Critical R002 rating)." *Id.* ¶ 308.
- By February 2006, Bard determined the G2 filter was migrating caudally and a "high percentage of caudal migrations accompanied by significant filter tilting and limb displacement." *Id.* ¶ 82. Bard concluded the severity of these occurrences was "critical." *Id.*
- By March 2, 2006, Bard determined the G2 filter propensity for caudal migration represented an "unacceptable risk" of serious injury and death. *Id.* ¶ 87. Nonetheless, Bard took no "preventative action" to warn physicians or patients about the "unacceptable risk." *Id.*
- In March 2006, internal emails at Bard described "a terrible situation [with Bard's IVC filters] that was held together with scotch tape, smoke, mirrors, crying, etc." *Id.* ¶ 46.
- In August 2006, the medical monitor for Bard's clinical retrievability study for the G2 filter expressed significant concern regarding the rate of tilt in the study and suggested Bard consider redesigning the filter at that point. *Id.* ¶ 91.
- Bard knew that fracture, tilt, and perforation were caused by migration, including caudal migration. *Id.* ¶¶ 79, 80, 81, 83, 84-88, 94-99.
- Bard knew the G2 filter had increased rates of caudal migration as compared to the Recovery. *Id.* ¶ 79, 80, 81, 83, 84-88, 94-99.
- Bard was aware that the physician perception was that "design sacrifices" were made for its optional filters that led to higher rate of movement or migration, which Bard knew led to an increased risk of fracture. *Id.* ¶ 99.
- Bard's internal analysis demonstrated that the Recovery filter fractured 55 times more often than the SNF; the G2 fractured more than 12 times as often as the SNF, the G2X fractured 10 times as often as the SNF, and the Eclipse, even after limited sales, fractured nearly 4 times as often as the SNF. *Id.* ¶ 114.
- Bard's retrospective analysis of its filter fractures groups the G2, G2X, and Eclipse together and shows that both the number of fractures and the cumulative fracture rate increased consistently over time. *Id.* ¶ 128. Thus, consistent with the later medical literature,[3] Bard knew that its filters fractured at an increasing rate the longer they stayed in the body.
- The independent medical monitor for Bard's EVEREST trial (which evaluated retrievability of its G2 filters, not long term safety and efficacy) indicated that approximately 20% of the filters in the trial tilted and thought Bard should consider a redesign of the G2 (which was already on the market). The same medical monitor questioned whether there was concern that 50% of the patients in the study reported and adverse event. *Id.* ¶91-92

[3] A 2009 study demonstrated that, after 180 days, Bard IVC filters began to fracture. *Id.* ¶ 98. A 2010 study demonstrated that Bard's filters had an increasing fracture rate over time and an expected fracture rate of approximately 25 percent at 50 months. *Id.*

- Neither the Recovery nor the G2 filters' IFUs contain warnings about migration, fracture, or perforation. The IFUs contain warnings about failure modes related to the implantation process but do not warn about these complications post-implantation. They (the IFUs) only indicate migration, fracture and perforation separate from the implantation process as "Potential Complications." *Id.* ¶74, Ex. 63.

Nonetheless, Bard never warned patients or physicians (before implant or after implant but before injury) that its filters, including the G2, had a greater risk of complications and failures than its competitors' devices and the SNF.

Furthermore, Bard's Instructions for Use ("IFU") for the G2 do not include warnings that its filters fractured, migrated, tilted, and perforated patients' IVCs at rates significantly higher than competitor IVC filters and Bard's SNF. *Id.* ¶ 74. Nor did they disclose that the filters caused an unreasonable risk of serious injury and death, as Bard had determined. *Id.* Dr. [redacted] testified that he read and relied upon the G2 IFU, thus, he was aware of only the potential complications of the G2 that were reported at the time of implant. OSOF-Supp. ¶ 331. Dr. [redacted], was not aware of the Crisis Management Plan in effect by Bard as early as 2004 to deal with the high rates of adverse events, perforation, fracture and migration. *Id.* ¶ 332. He was not aware that Bard in 2004, through an independent investigator, looked into the high number of adverse events of Recovery (the predicate to the G2 upon which the G2 was developed), nor was he informed of the results of that investigation. *Id.* ¶ 333. He was never told by his sales rep that there was a 530% higher fracture rate over other filters on the market for the Recovery or a 1200% higher risk of death from Recovery fracture and embolization to the heart. *Id.* ¶ 334. He testified he would have liked to have known this information in 2004-2005 before he [redacted] Ms. Booker [redacted]. *Id.*

Dr. [redacted] further testified that the adverse events analysis reports and the MAUDE information would have been important information to know and would have influenced his prescribing habits. *Id.* ¶ 335. He may have used a filter other than a Bard filter. *Id.* The information contained in the 2004 Health Hazard Evaluation ("HHE")

from David Ciavarella M.D., vice president of clinical affairs at Bard, showing higher fracture rates in the Recovery compared to other filters would have been important information for Dr. [redacted] to have. *Id.* ¶ 336. He would have liked to have known about the Recovery filter migration Remedial Action Plan from January 2005. *Id.* ¶ 337.

Dr. [redacted] testified, "With regards to the Bard filter, would I have used a different device if I knew at the time that the Bard filter was not ideal or as good as some of the other implants? The answer would have to be yes. I would have used a different filter if there was a different filter that I knew of that was better, in terms of its safety profile." *Id.* ¶ 338. When Dr. [redacted] was asked if he would have used a different filter if he knew all the information that the investigation revealed he responded: "Difficult to say with certainty. It would depend upon what other filters we had at the time and what their problems would have been. But it would have been a very important piece of information, as far as making decisions regarding this or any other patient, yes." He was further asked: "If you knew back in 2007 when you were implanting that filter that there was even a 12 percent probability of fracture with the filter, would you have used a G2?" His answer: "Unlikely" He was then asked: "if there was a 25 percent risk of filter fracture, can we safely say you would not have used that filter?" His answer: "Most likely." *Id.* ¶¶ 339, 340. Since the Booker implant, Dr. [redacted] has learned more about IVC filters and their complications and he has stopped using the Bard filters because of his own experiences with the high failure rates, MAUDE database reports, and the literature regarding filter fragmentation and migration. *Id.* ¶ 341.

Dr. [redacted] testimony is buttressed by that of Robert Ferrara, his Bard sales representative. Mr. Ferrara testified that radiologists and their support staff look to him for clinical knowledge at times, and that this knowledge potentially includes information about a product's strengths and weaknesses. *Id.* ¶ 345. He would need to give the physicians accurate information. *Id.* Mr. Ferrara would only convey to a physician information that was approved by Bard and he trusted Bard to give him the information that was important to pass along to the physicians. *Id.* ¶ 346.

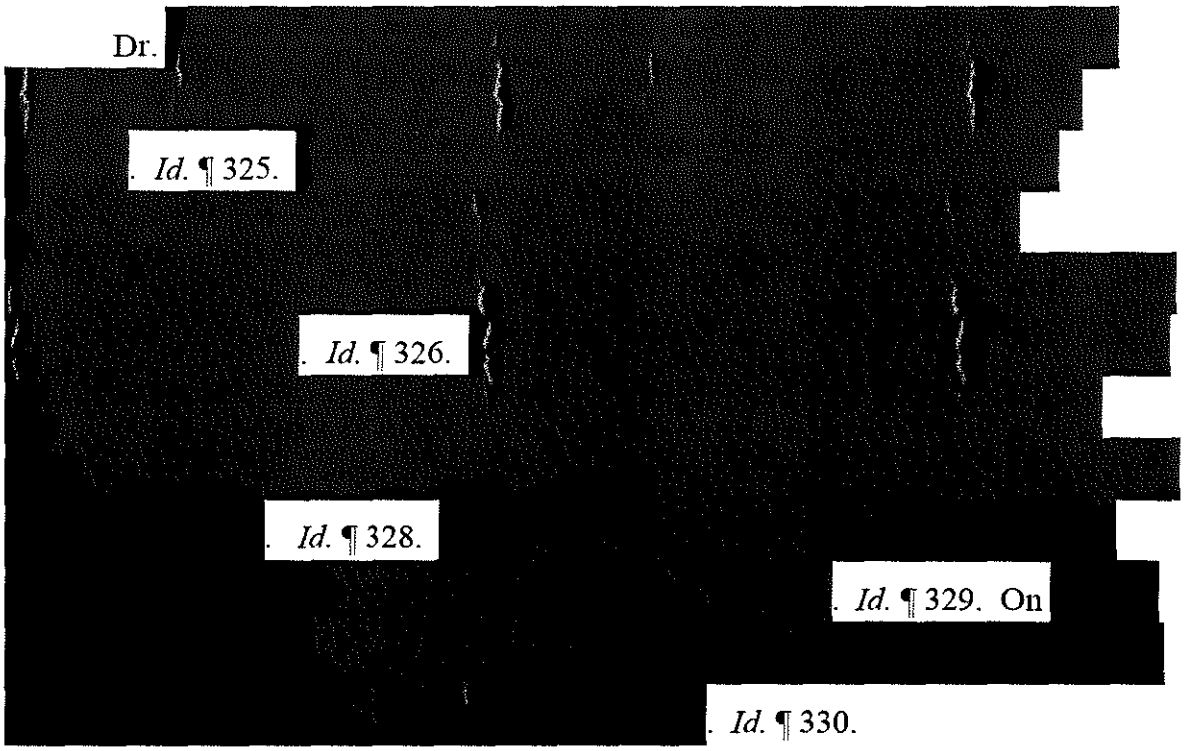
Mr. Ferrara would expect the marketing materials to be put out by Bard to be truthful and accurate. *Id.* ¶ 347. Mr. Ferrara admits that the G2 Patient Question and Answer Brochure states, "The G2 filter combines the best design features of Bard's existing vena cava filters to create a brand new permanent filter platform taking strength and stability to a new level." *Id.* ¶ 348. He states that the G2 was marketed as having reduced tilt and having increased fracture resistance. *Id.* ¶ 349.

He acknowledges that it is not a good idea to hide data or studies regarding a product from doctors yet Ms. Ferrara was never provided with the Asch study or the results thereof. *Id.* ¶¶ 350, 351. He does not recall being given any data or information about the comparison of migration rates of various filters. *Id.* ¶ 352. He was not aware that Bard had instituted a Crisis Plan regarding the Recovery filter in 2004. *Id.* ¶ 353. He was never shown any Health Hazard Evaluations prepared by Bard reflecting reports of serious injuries and deaths with Recovery and G2 filters. *Id.* ¶ 355. He was never shown the chart comparing G2 trends to Recovery, which chart shows that the G2 had more perforations, caudal migrations, and tilts. *Id.* ¶ 356. Since he never was told about this chart, he did not relay that information to Dr. [redacted]. *Id.* ¶ 357. Despite the fact that Bard was looking into a project to modify the G2 filter to minimize caudal migration in February 2006, and as late as 2012 Bard had no idea what was causing migrations related to its G2 filters knowing they could fail and cause less protection to the patient (*Id.* ¶359-365), Mr. Ferrara does not recall any specific discussions with any of the doctors at New York Methodist about issues with caudal migration in the G2 filter. *Id.* ¶ 358.

Bard witnesses and experts have expressed concerns about Bard's failure to disseminate important information to the medical providers, such as Dr. [redacted]. According to Dr. Clement Grassi, a Bard expert, informed consent requires taking into consideration what "a reasonable patient would want to know in the same or similar circumstances." OSOF ¶ 116(a). And, Bard's V.P. of Quality Assurance, Regulatory Affairs and Medical Affairs agreed Bard should have communicated to physicians and patients statistically significant findings that Bard's IVC filters had greater risks,

complications, and malfunctions than the SNF and competitor filters. *Id.* ¶ 115(a). Dr. Grassi agreed patients would want to know this kind of information in making risk/benefit determinations as to having the device implanted. *Id.* ¶ 116(d). Natalie Wong, Bard's marketing manager, also agreed. *Id.* ¶ 117. Similarly, John McDermott, BPV's President from 1999 through 2008, testified physicians would want to know this information and it is important to their decision making. *Id.* ¶ 121. But Bard failed to provide this known information, concealing it from physicians and patients who need it to make reasonable risk/benefit decisions. Similarly, Plaintiffs' and Bard's physician experts have testified that this type of information is important to treating physicians to determine the risk/benefit of using the device and in order to obtain appropriate informed consent from patients. *Id.* ¶¶ 309-310. Bard knew migration could lead to fracture and continued to develop subsequent filters while Ms. Booker still [redacted]. *Id.* ¶¶364, 366 - 367. Bard even began to develop a filter that attempted to address the known caudal migration issues the G2 family of filters were plagued with [redacted] and that its own experts were aware of such failures with little proven efficacy. *Id.* ¶369 - 373.

On [redacted]. OSOF-Supp. ¶ 319. She was [redacted]. *Id.* ¶ 320. A [redacted]. *Id.* ¶ 321. A [redacted]. *Id.* Ms. Booker was referred to Dr. [redacted]. *Id.* ¶ 322. Ms. Booker consulted with [redacted]. *Id.* ¶ 323. [redacted]. *Id.* ¶ 324.



III. Summary Judgment Is Not Appropriate on the Contested Claims

A. The Appropriate Standard on Summary Judgment Requires this Court to View the Facts in the Light Most Favorable to Plaintiff

Summary judgment is appropriate when no genuine issues of material fact exist and a party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In applying this standard, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Thus, if a reasonable trier of fact could find in favor of the non-moving party, summary judgment is improper. *Id.* at 248.

B. Bard Fails to Demonstrate Summary Judgment is Appropriate on Plaintiff's Failure to Warn (Counts II and VI) and Misrepresentation Claims (Counts VIII and XII)

Under Georgia law, a manufacturer breaches its duty to warn if it fails (1) to "adequately communicate the warning to the ultimate user or (2) fail[s] to provide an adequate warning of the product's potential risks." *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1219 (11th Cir. 1999) (quoting *Thornton v. E.I. Du Pont De Nemours & Co., Inc.*, 22 F.3d 284, 289 (11th Cir. 1994)). The duty to warn an end user of a risk associated with

product use arises "whenever the manufacturer knows or reasonably should know of a danger arising from the use of its product." *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994). Thus, the duty is a continuing one and may arise "months, years, or even decades after the date of the first sale of the product." *Watkins*, 190 F.3d at 1218.

"Under the learned intermediary doctrine, the manufacturer of a . . . medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003). "[U]nder the learned intermediary doctrine, the manufacturer's warnings to the physician must be adequate or reasonable under the circumstances of the case." *Id.* In Georgia, the general rule is that the adequacy of a warning is an issue for the jury. *Thornton*, 22 F.3d at 289 (citing *Watson v. Uniden Corp. of America*, 775 F.2d 1514, 1516 (11th Cir. 1985)). "Whether adequate efforts were made to communicate a warning to the ultimate user and whether the warning if communicated was adequate are uniformly held questions for the jury." *Id.*

1. Bard's warnings were inadequate because they did not include risk rates or disclose that the risk associated with Bard's devices were higher than those of competitor devices or the SNF.

Bard contends that it is entitled to summary judgment because its generic warnings that its filters may migrate, tilt, or fracture were "adequate" as a matter of law. In particular, Bard incorrectly suggests that it "can find no Georgia law creating a duty on a manufacturer to provide comparative rates of complication for its product to other similar products on the market." *Id.* at 8.[4] Bard and its counsel are well aware of the rulings in *Cason* and *Cisson* in which the courts rejected this very argument. In *Cason*, the court specifically found that there was a question of fact as to whether Bard's warnings for IVC filters were adequate because the warnings did not disclose that complication rates for the G2 filter were significantly higher than the rates for competitor IVC filters and the SNF.

[4] "Although Bard frames this argument as one of duty, it actually relates to whether Bard's warnings were adequate, which is a question of breach." *Cisson*, 2013 WL 5700513, at *7.

Cisson, 2013 WL 5700513, at *7. The same question of fact exists here as to Bard's label which fails to disclose that the G2 has significantly higher complication rates than the rates for competitor IVC filters and the SNF. Moreover, there were no actual warnings contained in the G2 IFU beyond the complications related to implantation; "potential complications" do not constitute a warning.

Under Georgia law, whether if a warning is provided (which it was not here) and it did not include a known rate or severity of potential injury, then whether the alleged warning is adequate is a question for the jury. *Thornton*, 22 F.3d at 289 (adequate warning "must provide a complete disclosure of the existence and extent of the risk involved."). Whether a device should include a warning that it carries an increased risk of a particular complication is particularly a question of fact for the jury. *See In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1378 (M.D. Ga. 2010) (holding reasonable jury could find warnings inadequate given manufacturer "did not inform Plaintiffs' physicians of any increased risks associated with ObTape"); *Watkins*, 190 F.3d at 1220 (finding genuine issue of material fact on failure-to-warn claim because jury could conclude that more adequate warning was needed on vehicle that had greater propensity than other vehicles to roll over).

Bard's IFU language indicated under the "Potential Complications" section that its filters may tilt, migrate, or fracture—complications that exist for all filters. They failed to warn that Bard's IVC filters tilt, migrate, and fracture at rates higher than competitor filters and Bard's SNF; they also failed to warn of Bard's conclusion that Bard's filters presented an unreasonable risk of serious injury and death. The failure to disclose higher complication rates than the SNF is particularly significant here as the G2 was only cleared for permanent use at the time of implants and there is evidence that Dr. [redacted] placed the [redacted]. Bard knew its G2 filters were failing and fracturing at rates higher than competitor devices and much higher than the SNF. A reasonable jury could certainly conclude that an adequate warning would include such information.

The precise warnings on which Bard relies and the arguments it makes here were at issue in *Cason*, 2015 WL 9913809. There, as here:

> Plaintiffs concede[d] that the IFU provides a list of potential complications of which [the implanting doctor] was aware, but they argue that the warnings were inadequate because they [the warnings] failed to disclose that the frequency with which these complications occurred with the G2 Filter was significantly higher than with other IVC filters manufactured both by defendants' competitors and defendants themselves.

Id. at *3. Citing *In re Mentor Corp. ObTape*, Judge Shoob of the Northern District of Georgia concluded "there is a genuine issue for trial as to whether the warnings provided by Bard were adequate." *Id.* Judge Shoob noted the evidence that (a) the G2 filter had "a significantly greater propensity to fracture, migrate, and perforate the IVC than other IVC filters," and (b) Bard "knew or should have known about the increased risks associated with the G2 Filter."

> Given this evidence, combined with the evidence that defendants did not warn Ms. Cason's doctor about any increased risk associated with the G2 Filter, a reasonable fact finder could conclude that the IFU did not contain an adequate warning regarding the G2 Filter.

Id. at **4-5

In *Cisson v. C.R. Bard, Inc.*, 2013 WL 5700513, Bard argued, as it does here, "that its duty was limited to warning about possible complications, not their rate or severity." *Id.* at *7. Applying Georgia law, the court found to the contrary: "Bard's warnings were adequate as a matter of law only if 'a reasonable jury would not have a legally sufficient evidentiary basis' to find against Bard." *Id.* at *8. Identifying evidence that Bard knew its device "created a higher risk of complications," the court found "sufficient evidence to create a jury question as to whether Bard's warning was adequate." *Id.*

Bard claims "Georgia law does not require a manufacturer to provide comparative rates of complication for its products," citing two cases—both of which inapposite to the argument it makes. The first, *Hoffman v. AC&S, Inc.*, 548 S.E.2d 379, 382 (Ga. App. 2001), did not involve a failure-to-warn claim. Rather, the court found that the plaintiff needed to establish that the product or products that allegedly caused her mesothelioma were manufactured or supplied by the defendants. Further, the language and pin cite Bard

uses for *Dixie Grp., Inc. v. Shaw Indus. Grp., Inc.*, 693 S.E.2d 888, 892 (Ga. App. 2010), relate to whether the defective product reached the user without substantial change in condition and had nothing to do with the failure-to-warn claim in that suit. Bard's other authorities are not Georgia law and are inconsistent with *Cason*, *Cisson*, *In re Mentor Corp. ObTape*, and *Watkins*.

2. Neither [redacted] nor the medical community was aware of the information Plaintiff contends should have been in Bard's warnings.

a. Dr. [redacted] was not aware.

Bard argues that because Dr. [redacted] had actual knowledge of the risk of fracture, there is no proximate cause for the failure-to-warn claims. Bard is wrong. There is no dispute Dr. [redacted] was aware the filter [redacted] Ms. Booker could fracture; nor is there any dispute that her filter's IFU included a risk of fracture as a potential complication. However, Plaintiff contends that under Georgia law, Bard's warnings were inadequate because they did not disclose that the risk of fracture for the G2 was greater than the risk of the same complication for its competitors' devices or as against the SNF. Dr. [redacted] was not aware of the rate of risk or that the rate was significantly higher than for other IVC filters. Dr. [redacted]a would have wanted to know the fracture-rate information.

Bard's citations to *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351 (N.D. Ga. 1999), and *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272 (11th Cir. 2002), are unavailing. In both cases, the courts found that the doctors were aware of the very warning the plaintiffs contended should have been given. *Wheat*, 46 F. Supp. 2d at 1363-64; *Ellis*, 311 F.3d at 1277, 1279 (both doctors and patient were aware that "only the patient should activate the PCA pump unless a doctor instructed otherwise."). That is simply not the case here.

b. There is no evidence that the medical community was aware.

Finally, Bard suggests that Plaintiff's failure-to-warn claims fail because the complications of its filters are well-known by medical professionals. Again, this argument is without merit. Plaintiff does not dispute that the medical community was

aware that IVC filters generally carry the risk of certain complications, including tilt, migration, and fracture. Plaintiff's argument is not that Bard's warnings were inadequate under Georgia law because they failed to disclose the *existence* of complications; Bard's warnings were inadequate because they did not warn about these complications other than related to implantation. Moreover, Bard neither warned doctors regarding the *rate* of these complications it knew about related to its filters nor disclosed that the rate of dangerous complications associated with Bard's devices were significantly higher than those of other IVC filters. Bard has failed to present undisputed evidence to carry its burden to establish that "medical professionals" were aware in June 2007 of the failure rates of Bard IVC filters or that the filters had a higher risk of complications than competitor devices and the SNF.

3. Plaintiffs' negligent and fraudulent misrepresentation claims likewise go to the jury.

Fraudulent misrepresentation claims survive summary judgment in Georgia. Bard cites *Brazil v. Janssen Research & Dev. LLC*, No. 4:15-CV-0204-HLM, 2016 WL 4844442, at *11 (N.D. Ga. Mar. 24, 2016), and *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008), for the proposition that Georgia does not recognize a claim for misrepresentation apart from a failure-to-warn claim. Those cases, however, do not support Bard's contention.

Swicegood involved an unusual set of facts and the court's reluctance to recognize a claim absent clear Georgia precedent. 543 F. Supp. 2d at 1357. There, a plaintiff sued a name-brand manufacturer for alleged misrepresentations in its warnings that caused the generic-brand manufacturer to supply plaintiff with inadequate warnings as to the generic medication. *Id.* Expressing reluctance to recognize an independent misrepresentation claim against the name-brand manufacturer who was not the manufacturer of the product at issue, the *Swicegood* court cited to *Potts v. UAP-GA AG CHEM, Inc.*, 567 S.E.2d 316, 318 (Ga. App. 2002). *Potts* upheld a negligent-misrepresentation claim against an employer who induced a physician to believe (falsely) that an employee had not been

exposed to chemicals, thus impairing the physician's treatment of the employee. *Id.* at 319-20. The *Swicegood* court acknowledged that "*Potts* itself contemplated that a misrepresentation claim could be distinct from a failure to warn claim[.]" 543 F. Supp. 2d at 1357. But the *Swicegood* court found the misrepresentation claim in that case was "masquerading" as a products-liability claim against a manufacturer whose product had not caused plaintiff's injuries; it concluded that liability for misrepresentation under those facts would have resulted in "an unprecedented departure from traditional Georgia tort law." *Id.*

In *Brazil*, the court dismissed the misrepresentation claim for different reasons, citing *Swicegood* in dicta as not supporting such a claim in lieu of a product-liability claim. 2016 WL 4844442 at *11.

C. Plaintiffs Have a Viable Claim for Negligence *Per Se* (Count IX).

Georgia has codified the doctrine of negligence *per se*. Under the Georgia statute:

> When the law requires a person to perform an act for the benefit of another or to refrain from doing an act which may injure another, *although no cause of action is given in express terms*, the injured party may recover for the breach of such legal duty if he suffers damage thereby.

Ga. Code Ann. § 51-1-6 (emphasis added); *St. Mary's Hosp. of Athens, Inc. v. Radiology Professional Corp.*, 421 S.E.2d 731, 736 (Ga. App. 1992). To establish negligence *per se* under Georgia statutory and common law, a plaintiff must demonstrate that (1) the injured person falls within the class of persons the statute was intended to protect and (2) the harm complained of was the harm against which the statute was intended to guard. *See Amick v. BM & KM, Inc.*, 275 F. Supp. 2d 1378, 1382 (N.D. Ga. 2003). When both criteria are met, the plaintiff has fulfilled the duty and breach elements of a negligence claim. *Id.*

Here, Count IX of Plaintiff's Master Complaint alleges that Bard was negligent *per se* and based upon violations of several sections of the Food Drug and Cosmetic Act including but not limited to, 21 U.S.C. §§ 321, 331 and 352, and various attendant regulations, specifically 21 C.F.R. §§ 1.21, 801, 803, 807 and 820.

Bard does not dispute Plaintiff's allegations that Sherr-una Booker falls within the class of persons these laws were intended to protect or that the harm she suffered from her Bard IVC Filter was the type of harm the statute the state laws were intended to guard against. Rather, Bard's sole challenge to Plaintiff's negligence per se count is Bard's suggestion the claim is preempted. There are two flaws in Bard's argument. First, Plaintiff's claims are not preempted. *See* Plaintiffs' Response in Opposition to Defendants' Motion for Summary Judgment Regarding Preemption ("Preemption Opposition") [Doc. 7369].

Second, Bard's attack relies exclusively on *Leonard v. Medtronic Inc.*, 2011 WL 3652311 (N.D. Ga. 2011). *Leonard* stated that "[a] private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist[.]" *Id.* at *7 (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). But, the district court's holding was predicated upon the finding that the *Leonard* claims were preempted by virtue of the fact that the subject medical device at issue in that case had undergone the rigorous premarket approval ("PMA") process. *Id.* at *8 (citing cases for proposition that plaintiffs cannot escape preemption by reference to FDCA provisions since there is no private right of action under FDCA). Thus, the *Leonard* plaintiffs could not resurrect otherwise preempted claims simply by calling them state-law negligence-based claims. *Leonard*, however, has no application to Plaintiff's claims here since Plaintiff's claims are based on devices that did not undergo PMA review and, therefore, are not preempted. *See generally* Preemption Opposition.

To the extent Bard suggests that *Leonard* established a broad rule that where a statute, regulation, or other type of law does not create a private right of action it cannot support a claim for negligence *per se*, it is wrong. Georgia common law and its statute expressly recognize that laws that do not create a private cause of action may nonetheless support a claim for damages. *See* Ga. Code Ann. § 51-1-6; *Amick*, 275 F. Supp. 2d at 1382. Such a sweeping rule would vitiate Georgia's common law and directly conflict

with the language of Georgia Code § 51-1-6. In the overwhelming majority of cases in which negligence per se applies, the subject statutes do not create private cause of action. Further, Section 51-1-6 expressly permits such claims. It is not, and cannot be, the rule that a statute must create a private cause of action in order to support a claim for negligence *per se*. *See, e.g., Amick*, 275 F. Supp. 2d at 1382-83 (noting that statutory obligations applicable to hotels and innkeepers could serve as basis for negligence *per se* claims brought by blind person for damages arising from conduct alleged to be in violation of these statutory duties).

D. There is Sufficient Evidence for Punitive Damages to Go to the Jury

Bard lastly contends that the Court should grant summary judgment on Plaintiffs' punitive damages claim, claiming Plaintiffs have not established by clear-and-convincing evidence that Bard's conduct warrants an award of punitive damages under Georgia law, and because Bard complied with federal regulations with respect to the Eclipse filter's 510(k) clearance submission and its labeling. Both arguments are wrong.

1. A jury could readily conclude that Bard's conduct warrants punitive damages.

In Georgia, punitive damages are available in tort actions "in which it is proven by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." O.C.G.A. 51-12-5.1(a). Willful or wanton behavior is not required; "an entire want of care and an indifference to consequences" is enough to support a punitive damages claim. *CSX Transp., Inc. v. West*, 523 S.E.2d 63, at 66 (Ga. App. 1999).

Bard's actions demonstrate an "entire want of care and an indifference to consequences" warranting imposition of punitive damages. Despite owning and selling an IVC filter that had a low incidence of complications and had never been associated with a patient death (the SNF), Bard recognized a financial opportunity to create a market for a "retrievable" filter by "aggressive marketing even in the absence of solid clinical history

and in spite of documented negative clinical experiences." OSOF ¶ 20. Thus, Bard developed the "Recovery" filter. *Id.* ¶¶ 6-8. The history of the Recovery filter is relevant and directly related to the safety profile of the G2 because it acted as the predicate filter for G2 and it was even known as the "G1A Recovery Filter". *Id.* ¶ 66, Ex. 62.

In its rush to get Recovery on the market, Bard cut significant corners. First, it never properly understood the environment of use for the IVC filters. Its Vice President of Research & Development admitted as much. *Id.* ¶ 37. And, internally, long before this lawsuit Bard admitted as much: "After a year of commercialization, there are still many questions that need to be answered." *Id.* ¶ 33(b). The Recovery failed internal tests and performed worse than the SNF. *Id.* ¶¶ 21, 34. And, just a month before full market release, its Special Design Review team raised serious questions and asked for "objective evidence" to support the safety and efficacy of the Recovery, including that certain criteria be supported and tests be done. *Id.* ¶¶ 29. But Bard never did any of those things before releasing the Recovery to the market. *Id.*

Bard also never did repeatable, long-term clinical trials regarding the safety of efficacy of its devices. And the one study it held raised serious concerns about the safety and efficacy of its product. Of the first 32 patients evaluated, there were two fractures in one device, one migration, two tilts, one perforation, and 19 deployment problems. *Id.* ¶ 10. As a result of the fractures, the Canadian Institutional Review Board suspended the study. *Id.* ¶ 11. Bard promised the physician who ran the study, Dr. Murray Asch, that would conduct additional safety studies before the filter was marketed. *Id.* ¶ 13. But it never did. And, contrary to Dr. Asch's testimony that his study should never have been used as a basis for market clearance of the Recovery, Bard used it for just that. *Id.* ¶ 12.

And, even before the Recovery went to full market release, Bard was already receiving reports of adverse events from the field. *Id.* ¶ 28. Despite these events, never identifying the root cause of the failures in the study (let alone an understanding of how the anatomy of the IVC actually performed in patients), and not conducting studies

requested by Bard design review team members, Bard pushed ahead to get the Recovery on the American market. *Id.* ¶ 50.

It was successful. Predicated on the claim that the Recovery was substantially equivalent to the SNF in terms of safety and efficacy, Bard obtained clearance from the FDA to market the Recovery filter through the 510(k) process as a permanent device on November 2002, and for optional retrieval on July 25, 2003. *Id.* ¶¶ 17, 18. As detailed in Section II, *supra*, and in Section I(B)-(F) of Plaintiffs' OSOF, Bard quickly obtained additional information of what it already knew but did not tell the public—the Recovery and subsequent filters were not the substantial equivalent of the SNF. Full market release of the Recovery was followed by significant migrations and fractures, including seven deaths the first year. OSOF ¶¶ 28, 31, 41, 48.

Based on reporting and internal analysis, it was fully aware that the Recovery and G2 were dramatically inferior to Bard's SNF and most competitor devices in terms of migration, tilt, perforation, and fracture. *Id.* ¶¶ 33-38, 40, 49, 57, 60, 62, 66, 78, 97,104. In early 2004, it learned that its products' design did not account for how the IVC actually performed and that its devices were causing injury and death at alarming rates. *Id.* ¶¶ 29, 41, 53. In the face of mounting reports of injury and death, and increasing physician and patient complaints, instead of taking its product off the market or warning the medical community of the dangers of its retrievable line of IVC filters, Bard actively sought to keep the medical community in the dark and protect its products' reputation. It hired outside public relations specialists to help Bard develop a Crisis Communication Plan to control messaging to physicians and media (e.g., "downplay[ing]" "comparison with other filters [because it was] problematic in many ways"). *Id.* ¶ 45. It misled its own internal employees, *id.* ¶ 52, and sales representatives concerning dangers and failure rates. *Id.* ¶¶ 107, 131-49.

And, rather than pull its devices off the market, Bard engaged in a campaign of offering newer but equally defective designs to maintain its position in the market. In 2005, after the Recovery's mounting number of fractures, migrations, and deaths, Bard

redesigned the filter to the G2 but never adequately tested the device to determine whether it actually fixed the problems. Indeed, it actively avoided certain tests for fracture resistance because it knew the results "would still fall outside of the acceptable range" and its engineers "didn't think the answer would support our design change as a viable option." *Id.* ¶ 76. Nonetheless, Bard pressed forward. Even when its internal analysis and the EVEREST study demonstrated significant complications with the G2 (even greater than the Recovery for several of them), *id.* ¶¶ 84, 90-93, and that the caudal migrations (which can cause perforation and fracture) presented an "unacceptable risk" of harm, *id.* ¶ 87, Bard continued its marketing and sale of the product. Indeed, even when, in 2008, it identified significant design changes to the G2 that were essential to the safety of the device, *id.* ¶ 94, it did not notify doctors or remove the product from the market. It kept selling.

Thus, despite the fact that Bard knew that its retrievable IVC filters: (1) had never been adequately tested clinically for safety and efficacy; (2) were vastly less safe and efficacious as the SNF; (2) were failing at a rate substantially higher than its competitors; and (3) were injuring and killing patients, Bard never: (a) identified the root cause of its filters' many failures; (b) provided the medical community or regulators with adequate, let alone complete, disclosure of the damning information described above and in the OSOF; (c) recalled its filters (instead allowing prior devices to simply run out); (d) suspended sales of its retrievable IVC filters; or (e) implemented known design improvements to address alarming rates of filter migration and perforation. Succinctly, Bard's profit-driven acts and conscious omissions demonstrate that "entire want of care which would raise the presumption of conscious indifference to consequences."

2. Plaintiff disputes that Bard complied with federal law, but even if it did, compliance with federal law would not insulate Bard from punitive damages here.

Bard's claim that its alleged compliance with federal regulations insulates it from punitive damages here is wrong. Where a manufacturer "engaged in a deliberate course of conduct which knowingly endangered those using the product," punitive damages may

lie despite the manufacturer's compliance with applicable federal regulations. *Uniroyal Goodrich Tire Co. v. Ford,* 461 S.E.2d 877, 884 (Ga. App. 1995), *rev'd in part on other grounds by Ford v. Uniroyal Goodrich Tire Co.,* 476 S.E.2d 565 (1996).

For example, a punitive damages award against General Motors was upheld despite its compliance with safety standards because there was evidence that it had rejected safer designs "because of economic considerations." *General Motors Corp. v. Moseley,* 447 S.E.2d 302 (Ga. App. 1994), *abrogated on other grounds by Webster v. Boyett,* 496 S.E.2d 459 (Ga. 1998). Likewise, a tire manufacturer's motion for summary judgment on a punitive damages claim was denied because, even though it complied with the relevant federal safety standards, there was evidence it knew of separation defects with its tires' treads, had "refused to implement simple, relatively inexpensive solutions" because of profit margin concerns, and other tire manufacturers had adopted the safer designs. *Mascarenas v. Cooper Tire & Rubber Co.,* 643 F. Supp. 2d 1363, 1374 (S.D. Ga. 2009).

Tellingly, Judge Shoob, after evaluating a less developed factual record than that set forth in Plaintiffs' OSOF, rejected precisely the same arguments Bard asserts here:

> Defendants argue that punitive damages are not warranted because there is no evidence they acted with any malice, fraud, or oppression or deliberately to cause damage or interfere with plaintiffs' rights, and because they complied with all applicable FDA regulations. Compliance with federal regulations, however, is not sufficient to automatically preclude an award of punitive damages. *See* Cisson, 2013 WL 5700513, at *11–*12. Moreover, plaintiffs rely on the "conscious indifference" prong of the statute, which defendants' argument does not directly address. . . . Under the "conscious indifference" prong, "[n]umerous Georgia cases have held that punitive damages are available where a manufacturer knows that its product is potentially dangerous and chooses to do *nothing* to make it safer or to warn consumers." *Id.* at *13 (citations omitted) (emphasis in original). As discussed above, when viewed in the light most favorable to plaintiffs, there is sufficient evidence in the record to permit a reasonable fact finder to conclude that defendants knew the G2 Filter was failing at a significantly higher rate than other IVC filters but did nothing to correct the problem or to warn doctors or patients of the increased risk. Therefore, viewing the evidence most favorably to plaintiffs, a reasonable jury could find that punitive damages are warranted because defendants' conduct exhibited an entire want of care raising the presumption of conscious indifference to the consequences.

Cason, 2015 WL 9913809, at *6.

a. Bard placed profit over patient safety.

There is clear and convincing evidence from which a jury can conclude that Bard (like General Motors in *Moseley* and Cooper Tire in *Mascarenas*) acted out of a motive for profit over patient safety. Its plan was to sell retrievable filters using "aggressive marketing even in the absence of solid clinical history and in spite of documented negative clinical experiences." Indeed, contrary to promises to Dr. Asch—after his trial had multiple device failures, including a fracture—Bard never conducted safety and efficacy studies and took the Recovery to market without evidence it was actually safe. And, when patient deaths and filter failures mounted, instead of notifying doctors, Bard hired spin doctors to control the message and continued to sell—Beta testing its filters on unwitting human patients. Rather than recalling its filters or stopping sales, Bard kept its products on the market and just changed names—making "design changes" that were neither proven nor even necessarily aimed to correct the significant problems.

b. Bard did not comply with applicable federal regulations.

Moreover, there is significant evidence controverting Bard's *pro forma* contention that it complied with federal regulations concerning its 510(k) submission and device labeling. *See* OSOF ¶¶ 14, 88, 186-190.

Bard's submissions for the retrievable filters all required that they be substantially equivalent to their predicate devices. 21 C.F.R. § 807.87(f). All the filters tie back to the SNF as their predicate device (either directly or through their predicate device). And, the evidence demonstrates conclusively that the retrievable IVC filters were not the substantial equivalent of the SNF. OSOF ¶ 33-38, 40, 49, 57, 60, 62, 65, 66, 78, 97,104.

Bard also had an obligation to provide the FDA with honest and complete information in its 510(k) submissions and labeling. *Id.* ¶¶ 70, 75; 21 CFR § 807.87(k). The evidence described above establishes that Bard did not submit substantial adverse information with respect to its IVC filters or to alert the FDA that its retrievable filters were not the substantial equivalent of their predicate device, making Bard's 510(k) submission both false and incomplete.

IV. Conclusion

For the reasons discussed above, this Court should deny Bard's Motion, except as to Counts I and V (Manufacturing Defect) and VI (Failure to Recall/Retrofit), which Plaintiff withdraws.

RESPECTFULLY SUBMITTED this 12th day of October 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of October 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti